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EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,079	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Marc A Patterson	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112, second paragraph rejection of Claims 1 – 34, of record on page 2 of the previous Action, is withdrawn.

The 35 U.S.C. 102(b) rejection of Claims 1 – 7, 14 and 20 – 33 as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269), of record on page 2 of the previous Action, is withdrawn.

The 35 U.S.C. 103(a) rejection of Claims 8 – 9 and 18 – 19 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269), of record on page 4 of the previous Action, is withdrawn.

The 35 U.S.C. 103(a) rejection of Claims 20 – 22 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269), of record on page 5 of the previous Action, is withdrawn.

The 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527), of record on page 6 of the previous Action, is withdrawn.

The 35 U.S.C. 103(a) rejection of Claim 34 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S. Patent No. 6,348,568), of record on page 7 of the previous Action, is withdrawn.

NEW OBJECTIONS

Claim Objections

2. Claims 1 – 34 are objected to because of the following informalities: The test conditions of DIN EN ISO 527-1 to 527-3 have not been defined in Claim 1, therefore the meaning of the phrase ‘according to DIN EN ISO 527-1 to –3 1996’ is unclear. For purposes of examination, the claimed film will be interpreted to display no measurable yield under any test. The meaning of the phrase ‘hot water spraying process’ in Claim 1 is also unclear, as the process steps have not been defined in the claim or specification. For purposes of examination, the phrase ‘hot steam sterilization’ will be interpreted to mean any sterilization process. Appropriate correction is required.

3. Claim 14 is objected to because of the following informalities: The meaning of the phrase ‘when measured separately’ is unclear as the claim does not define the test conditions or whether the conditions are the same as in Claim 1. For purposes of examination, the layer will be assumed to have no measurable yield under the test conditions of Claim 1. Appropriate correction is required.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 – 9, 14 and 20 – 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080).

With regard to Claims 1 and 14, Heilmann et al disclose a film comprising three layers, an outer layer, supporting layer and a middle layer between the two layers (the middle layer is termed the central layer; column 3, lines 31 – 32); the outer layer and supporting layer are identical (column 3, lines 31 – 32) the supporting layer is therefore an inner layer, opposite the outer layer, having the same composition; the outer layer comprises polypropylene alone (column 5, lines 30 – 35 and the middle layer comprises polypropylene or a polypropylene blend (column 5, lines 43 – 45) and the inner layer consists of polypropylene (column 5, lines 46 – 50); the three layers therefore consist of 100% polypropylene materials; the film is sterilized with hot steam at 121 degrees Celsius (column 9, lines 14 – 16). Heilmann et al fail to disclose a laminate that displays no measurable yield point.

Collette et al teach a polypropylene (page 1, line 5) that shows no yield point, and therefore displays no measurable yield point (page 1, line 54) for use in the making of films (page 4, lines 18 – 19) for the purpose of obtaining films having high extensibility (page 4, line 25). One of ordinary skill in the art would therefore have recognized the advantage of providing for the polypropylene of Colette et al which displays no measurable yield point, as the

polypropylene in Heilmann et al, depending on the desired extensibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polypropylene which displays no measurable yield point in Heilmann et al in order to obtain a film having high extensibility as

taught by Colette et al, thus obtaining a multi – layer film having no measurable yield point; the film taught by Collette et al displays no yield following exposure to temperature above 121 degrees Celsius (after hot compression molding at 180 degrees Celsius; page 9, lines 51 – 55) and therefore displays no yield following sterilization at 121 degrees Celsius.

With regard to Claims 2 – 4, the proportion of the thickness represented by the middle layer is 70% (column 4, lines 8 – 17).

With regard to Claims 5 – 6, the proportion of the thickness represented by each of the the outer layer an inner layer is 15% (column 4, lines 8 – 13).

With regard to Claim 7, the total thickness of the film is 130 μm (column 4, lines 8 – 13).

With regard to Claims 8 – 9, Heilmann et al fail to disclose a total thickness in the range between 170 and 230 μm . However, Heilmann et al disclose a middle layer thickness of at least 90 μm (column 4, lines 10 – 11) and teaches the selection of layer thickness to avoid deformation of the middle layer under the action of heat (column 4, lines 13 – 17).

Therefore, one of ordinary skill in the art would have recognized the utility of varying the thicknesses of the layers of the film, and therefore the total thickness of the film, to limit the deformation of the middle layer as desired. Therefore, the deformation of the middle layer would be readily determined through routine optimization of thickness by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the thickness in order to obtain a desired limiting of the deformation of the middle layer, since the limiting of the deformation of the middle layer would be readily determined through routine optimization by

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one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 18, Heilmann et al fail to disclose an outer layer having a melting point that is greater than the melting point of the inner layer. However, Heilmann et al disclose that both layers contain polymers having melting temperatures greater than 121 degrees Celsius (column 4, lines 4 – 7) and that the melting point is selected so that the outer and inner layers support and stabilize the middle layer (column 3, lines 40 – 42). Therefore one of ordinary skill in the art would have recognized the utility of varying the melting temperatures of the polymers to obtain a desired stability of the middle layer. Therefore, the desired stability of the middle layer would be readily determined through routine optimization of the melting temperature of the polymers by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the melting temperatures of the polymers in order to obtain a desired stability of the middle layer, since the stability of the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 19, Heilmann et al fail to disclose a melting point of the middle layer that is less than the melting point of the outer layer and greater than the melting point of the inner layer. However, Heilmann et al disclose an outer and inner layer comprising polymers that have a softening temperature greater than 121 degrees Celsius and polymers that have a softening point less than 121 degrees Celsius (the layers adjacent to the central layer have a softening temperature of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius; column 4, lines 4 – 7) and Heilmann

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et al teach that the softening temperatures are selected in order for the outer and inner layers to provide desired support to the middle layer (column 3, lines 62 – 67; column 1, lines 1 – 3).

Therefore, one of ordinary skill in the art would have recognized the utility of varying the softening temperature of the components having a softening temperature less than 121 degrees Celsius to provide desired support to the middle layer. Therefore, the desired support provided to the middle layer would be readily determined through routine optimization of softening temperature by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the softening temperature of the components having a softening temperature less than 121 degrees Celsius in the outer and inner layers, and therefore the lowest melting temperature of the outer and inner layers, and therefore the melting point of the outer and inner layers, in order to provide desired support to the middle layer, since the support to the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claims 20 – 22, the middle layer disclosed by Heilmann et al has a Vicat temperature of 55 degrees Celsius (Vicat A = 55 degrees Celsius; column 8, lines 11 – 15), which is in the range from 35 degrees Celsius to 75 degrees Celsius. Heilmann et al also disclose outer layers and inner layers having Vicat temperatures of less than 121 degrees C, as discussed above (the layers adjacent to the central layer have a softening temperature, therefore a Vicat temperature, of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius; column 4, lines 4 – 7).

With regard to Claim 23, as discussed above with regard to Claim 1, the outer layer, middle layer and inner layer disclosed by Heilmann et al consist of polypropylene; the polypropylene is polypropylene homopolymer, in the outer layer (column 5, line 30), middle layer (column 5, line 39) and inner layer (column 5, line 48).

With regard to Claim 24, Heilmann et al fail to disclose a layer that consists of 70 – 90% polypropylene homopolymer. However, Heilmann et al disclose an inner layer consisting of polypropylene homopolymer, as discussed above, and Heilmann et al teach that the composition of the inner layer is selected to provide flexibility and clarity to the inner layer (column 5, lines 24 – 29). Therefore one of ordinary skill in the art would have recognized the utility of varying the amount of polypropylene to obtain a desired flexibility and clarity. Therefore, the flexibility and clarity would be readily determined through routine optimization of the amount of polypropylene by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the amount of polypropylene in order to obtain a desired flexibility and clarity, since the flexibility and clarity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 25, the middle layer disclosed by Heilmann et al comprises styrene – ethylene / butylene – styrene block copolymer (column 5, lines 36 – 41) and Heilmann et al teach that the inner layer comprises 70% by weight of the composition of the middle layer, to improve adhesion between the two layers (column 6, lines 1 – 6). Heilmann fails to disclose an inner layer comprising 10 – 30% by weight styrene – ethylene / butylene – styrene block

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copolymer. However, Heilmann et al teach the selection of the amount of styrene – ethylene / butylene – styrene block copolymer to improve adhesion between the two layers (column 6, lines 1 – 6). Therefore one of ordinary skill in the art would have recognized the utility of varying the amount of styrene – ethylene / butylene – styrene block copolymer to obtain a desired adhesion. Therefore, the adhesion would be readily determined through routine optimization of the amount of styrene – ethylene / butylene – styrene block copolymer by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the amount of styrene – ethylene / butylene – styrene block copolymer in order to obtain a desired adhesion, since the adhesion would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al

With regard to Claim 26, Heilmann et al also disclose a five layer film (column 3, line 62) comprising two layers having the composition of the middle layer and a layer having a polymer with a softening temperature of above 121 degrees Celsius between the two layers (column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening temperatures above 121 degrees Celsius (column 3, lines 31 – 36); Heilmann et al therefore disclose a five layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 27, Heilmann et al also disclose a seven layer film (column 3, line 62) comprising three layers having the composition of the middle layer and two layers having a polymer with a softening temperature of 121 degrees Celsius arranged between the three layers

(column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening points above 121 degrees Celsius (column 3, lines 31 – 36); Heilmann et al therefore disclose a seven layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 28, Heilmann et al disclose a method of producing the film comprising co – extruding the layers (column 6, lines 17 – 21).

With regard to Claims 29 – 31, the film disclosed by Heilmann et al is co – extruded as a flat film (column 6, lines 15 – 16); the film is therefore joined as a flat film, because in the process of co – extrusion the layers are joined to form the multi – layer film.

With regard to Claim 32, the film disclosed by Heilmann et al is suitable for contact with foodstuffs (column 7, lines 64 – 66) and Heilmann et al discloses that the use of multi – layer films in the packaging of foodstuffs (column 1, lines 16 – 20); Heilmann et al therefore disclose a packaging comprising the disclosed film.

With regard to Claim 33, the packaging stores parenteral solutions (it is appropriately suitable for contact with parenteral solutions; column 7, lines 64 – 67), and also stores water (it is formed into a bag which is filled with water; column 8, lines 58 – 63) and therefore stores water – based parenteral fluids.

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6. Claims 10 – 13 and 15 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and further in view of Fujii et al (European Patent No. 0838321).

Heilmann et al and Colette et al disclose a film comprising polypropylene as discussed above. With regard to Claims 10 – 13 and 15 – 17, Heilmann et al fail to disclose a film having an elasticity modulus of the middle layer that is less than 100 MPa and an elasticity modulus of the material of the outer layer that is greater than 400 MPa.

Fujii et al teach a polypropylene film (sheet; page 29 – 30) having an elasticity modulus (elastic modulus; page 4, lines 31 – 32) of 20 to 1000 MPa (page 2, line 39) for the purpose of obtaining a film that is soft and transparent (page 4, line 29). One of ordinary skill in the art would therefore have recognized the advantage of providing for the modulus of elasticity of 20 to 1000 MPa of Fujii et al in the layers of Heilmann et al and Colette et al, which comprises a polypropylene film, depending on the desired softness and transparency of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for an elasticity modulus (elastic modulus; page 4, lines 31 – 32) of 20 to 1000 MPa in Heilmann et al and Colette et al in order to obtain a film that is soft and transparent as taught by Fujii et al. The range of elasticity moduli of the layers would therefore include the claimed ranges of less than 100 MPa and greater than 400

MPa.

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7. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and further in view of Andersson et al (U.S. Patent No. 6,322,739 B1).

Heilmann et al and Colette et al disclose packaging comprising polypropylene as discussed above. Heilmann et al and Colette et al fail to disclose a packaging that stores fluid lipophilic emulsions.

Andersson et al teach a packaging (a container having stored fluid; column 4, lines 67) comprising polypropylene (column 4, lines 39 – 41) that stores fluid lipophilic emulsions (column 3, lines 20 – 23) for the purpose of obtaining a package having good compatibility with fluid lipid emulsions (column 3, lines 20 – 21). One of ordinary skill in the art would therefore have recognized the advantage of providing for the packaging of Andersson et al that stores fluid lipophilic emulsions, in Heilmann et al and Colette et al, which is a packaging comprising polypropylene, depending on the desired compatibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a packaging that stores fluid lipophilic emulsions in Heilmann et al and Colette et al in order to obtain a package having good compatibility as taught by Andersson et al.

ANSWERS TO APPLICANT'S ARGUMENTS

8. Applicant's arguments regarding the 35 U.S.C. 112, second paragraph rejection of Claims 1 – 34, 35 U.S.C. 102(b) rejection of Claims 1 – 7, 14 and 20 – 33 as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 8 – 9 and 18 – 19 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a)

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rejection of Claims 20 – 22 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527), and 35 U.S.C. 103(a) rejection of Claim 34 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S. Patent No. 6,348,568), of record in the previous Action, have been considered and have been found to be persuasive. The rejections are therefore withdrawn. The new 35 U.S.C. 103(a) rejection of Claims 1 – 9, 14 and 20 – 33 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and further in view of Fujii et al (European Patent No. 0838321) and Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and further in view of Andersson et al (U.S. Patent No. 6,322,739 B1) above are directed to amended Claims 1 – 34.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc Patterson 9/30/04

Marc A Patterson, PhD.

Examiner

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